

CANNON BUILDING
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STATE OF DELAWARE
BOARD OF PHARMACY

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PUBLIC MEETING NOTICE:	BOARD OF PHARMACY
DATE AND TIME:	Wednesday, August 20, 2014 9:30 am
PLACE:	Conference Room A, 2 nd Floor Cannon Building 861 Silver Lake Blvd., Dover, DE 19904
APPROVED:	September 17, 2014

MEMBERS PRESENT

Joli Martini, R.Ph., PharmD, Professional Member, President
Kimberly Robbins, R.Ph, Professional Member, Vice President
Sandra Zaragoza, R.Ph, Professional Member
Susan Esposito, R.Ph, Professional Member
Bonnie Wallner, R.Ph, Professional Member
Kenneth Sellers, Public Member
Jay Galloway, Public Member
David W. Dryden, R.Ph., J.D., Executive Secretary

MEMBERS ABSENT

Tejal Patel, R.Ph, PharmD, Professional Member

DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT

David Mangler, Director, Division of Professional Regulation
Eileen Kelly, Deputy Attorney General
Christine Mast, Administrative Specialist III
Michelle McCreary, Pharmacy Compliance Officer

ALSO PRESENT

Nancy Sawyer
Jaime Frink
Sandra Robinson
Kevin Musto
Jacob Grobelny
Lorraine S Massey
Letitia Kanar
Dora Temple
Eric Bravich
Christopher Hamilton
Christa Lee
Lisa Schieffert
Tiffany Sorey

Kevin Morgan
Julie Miro Wenger
Haley L Kavelak
Gayleen Philips
Anne Marie Pyle

CALL TO ORDER

Ms. Martini called the meeting to order at 9:32 a.m.

REVIEW OF MINUTES

A motion was made by Ms. Esposito, seconded by Ms. Zaragoza, to approve the meeting minutes for June 18, 2014. The motion unanimously carried.

PRESIDENT'S REPORT

Ms. Martini reported that pharmacy inspections have increased with the assistance of Michelle McCreary Pharmacy Compliance Officer. Ms. Martini expressed that this would be her last meeting as board president provided nominations and elections of new officers are completed later in the meeting.

UNFINISHED BUSINESS

Complaint Status

13-03-11 – Assigned to Hearing Officer
13-09-11 – Assigned to Hearing Officer
13-12-11 – Forwarded to Office of Attorney General
13-19-11 – Forwarded to Office of Attorney General
13-09-12 – Assigned
13-01-13 – Forwarded to Office of Attorney General
13-02-13 – Assigned
13-03-13 – Assigned
13-04-13 – Forwarded to Office of Attorney General
13-05-13 – Assigned
13-06-13 – Forwarded to Office of Attorney General
13-07-13 – Assigned
13-08-13 – Assigned
13-09-13 – Assigned
13-11-13 – Forwarded to Office of Attorney General
13-13-13 – Forwarded to Office of Attorney General
13-14-13 – Assigned
13-15-13 – Assigned
13-16-13 – Assigned
13-17-13 – Assigned
13-18-13 – Assigned
13-19-13 – Assigned
13-20-13 – Assigned
13-21-13 – Assigned
13-22-13 – Assigned
13-23-13 – Assigned
13-24-13 – Assigned

Re-Review of Consent Agreement – Anthony Franzosa

A motion was made by Mr. Sellers, seconded by Ms. Esposito, to approve the Consent Agreement. Ms. Wallner requested to be recused. The motion carried.

Review of Applications for Final Denial

None

Re-Review of Tabled Applications

Facility: Premium Rx National, a motion was made by Ms. Robbins, seconded by Ms. Zaragoza, to approve the application. The motion unanimously carried.

Facility: Central Rexall Drugs, Inc., a motion was made by Ms. Zaragoza, seconded by Mr. Galloway, to approve the application. The motion unanimously carried.

During the review process of the applications above discussion resulted concerning the questions on the applications and the misinterpretation of question 34 of the Non Resident Pharmacy Permit application. The clarification should address the need to disclose any discipline action to include facility, corporation or parent company. Ms. Mast will provide the board the updated question information during its next scheduled meeting. A motion was made by Ms. Robbins, seconded by Mr. Sellers, to update question 34 on the Non Resident Pharmacy Permit application to include the parent corporation disclosure information on the application. The motion unanimously carried.

Review of Practitioner/Pharmacy Ownership

Mr. Dryden provided the board a handout showing the number of other states that currently have a practitioner pharmacy ownership restriction. One third of the states have regulation in place prohibiting practitioners from having ownership in a pharmacy. A motion was made by Ms. Robbins, seconded by Ms. Wallner, in favor of drafting statute to place prohibitions on practitioner ownership of a pharmacy to be presented to other healthcare identities. The motion unanimously carried.

24 Del. C. §2512 Issuance and Renewal of Licensure Review

Mr. Dryden reported that an alert was sent regarding HB154 with amendments regarding continuing education requirements.

Nominations for Board President & Vice President

Ms. Martini nominated Mr. Sellers for President; the motion was seconded by Ms. Esposito. The motion unanimously carried.

Ms. Wallner nominated Ms. Zaragoza as Vice President, Ms. Zaragoza respectfully declined.

Ms. Martini nominated Ms. Esposito as Vice President; the motion was seconded by Mr. Sellers. The motion unanimously carried.

NEW BUSINESS

Ms. Martini read into the record the ratifications.

Pharmacist and Intern Licensure Approval Ratifications

Pharmacist:

A1-0004586	Rosemary A. Spiccioli
A1-0004587	Liza D. Nguyen
A1-0004588	Bruce Roberts
A1-0004589	Amber L. Myers
A1-0004590	Charlotte J. Lopacki
A1-0004591	Russell E. Farmer
A1-0004592	Maggie Yan Yu Chan
A1-0004593	Rachel M. Bounds
A1-0004594	Yanle Huang
A1-0004595	Dante A. Gravino
A1-0004596	Nicholas John Juliano
A1-0004597	Krista N Taylor
A1-0004598	Ona Peter Olaye
A1-0004599	Robert D. Matza
A1-0004600	Daniel P. Hines
A1-0004601	Theresa M. Ebinger
A1-0004602	Hyeyoon Choi
A1-0004603	Nayoon Choi

A1-0004604	Krystal T. Canally
A1-0004605	Lindsay D. McDonnell
A1-0004606	Caragh E. Clayton
A1-0004607	Brittany Ann Wilson
A1-0004608	Kenneth H. Harrington
A1-0004609	Colleen A. Herman
A1-0004610	Nur Nazih Kazzaz
A1-0004611	Eucharía A. Onu
A1-0004612	Amar S. Patel
A1-0004613	Benjamin D. Forrest
A1-0004614	Lauren E. Buchbinder
A1-0004615	Ashley H. Tillman
A1-0004616	Belayneh N. Endalew
A1-0004617	Christopher P. Shelton
A1-0004618	Suk J. Yom
A1-0004619	Camille R. King
A1-0004620	Derek S. Krajek
A1-0004621	Angela R. Lentini
A1-0004622	Hyungchul P. Kim
A1-0004623	Stephanie A. Kuratnick
A1-0004624	Chintan Rana
A1-0004625	Karen R. McKently
A1-0004626	Marianna S. Koerner
A1-0004627	Tara J. Petrucci
A1-0004628	Brooke E. Shaner
A1-0004629	Dennis C. Murphy
A1-0004630	Laura M. Hallisey
A1-0004631	Loretta Bienih
A1-0004632	Andrea J. Passarelli
A1-0004633	Lisa L. Deal
A1-0004634	Lisa M. Hutchins
A1-0004635	Stephanie E Perillo
A1-0004636	Katherine L. Trexler
A1-0004637	Belynda N. Sanders
A1-0004638	Clara J. Lee
A1-0004639	Karrisa L. Tocyloski
A1-0004640	Radhika K. Patel
A1-0004641	Jaclyn R. Beckett
A1-0004642	Ifeanyi Kingsley Mmagu
A1-0004643	John R. Kubota
A1-0004644	Rebecca Burris
A1-0004645	Kavita Patel
A1-0004646	Leslie M. Dykes
A1-0004647	Maelen G. Ignacio
A1-0004648	Darrall T. Heaton, Jr.
A1-0004649	Laura A. Falconieri
A1-0004650	An Thuy Nguyen
A1-0004651	Matthew D. Balish
A1-0004652	Ryan Michael Fillis
A1-0004653	Annmarie R. Tiangco
A1-0004654	Hey Sun Um
A1-0004655	Yun K. Hong
A1-0004656	Lauren Marie Navarre
A1-0004657	Miranda R. O'Brien

A motion was made by Ms. Zaragoza, seconded by Ms. Esposito to approve the ratification of the Pharmacist applications. The motion unanimously carried.

Pharmacist Intern:

A7-0002371	Kyle D. Massey
A7-0002373	Christina Ly
A7-0002374	Tam Bao Nguyen

A motion was made by Ms. Zaragoza, seconded by Ms. Esposito to approve the ratification of the Pharmacist Intern applications. The motion unanimously carried.

Non-Resident Pharmacy Licensure Approval Ratifications

A9-0001459	One Stop Rx, LLC
A9-0001458	Scripte Corporation
A9-0001460	Integrated Care Pharmacy
A9-0001461	Shiva Shakthi, LLC
A9-0001462	Pharmacy Creations, LLC
A9-0001463	DermaTran Health Solutions
A9-0001464	White Drug #61
A9-0001465	Vet Meds N More, Inc. dba National Animal Hospital
A9-0001466	LCRx, LLC
A9-0001467	American Custom Compounding Pharmacy, LLC
A9-0001468	Renner Pharmacy Inc
A9-0001469	Smartscrip Pharmacy
A9-0001470	SmartPractice Allergen Bank, LLC
A9-0001471	University Compounding Pharmacy
A9-0001472	Primrose Pharmacy, LLC
A9-0001473	University Compounding Pharmacy
A9-0001474	Med Care Choice Pharmacy, Inc
A9-0001475	Absolute Pharmacy LLC
A9-0001476	Oldsmar Pharmacy
A9-0001477	My Script, LLC
A9-0001478	Solara Medical Supplies
A9-0001479	Amber Pharmacy
A9-0001480	Amber Pharmacy
A9-0001481	Express Scripts Pharmacy, Inc. dba Express Scripts
A9-0001482	Hunter's Specialty Pharmacy
A9-0001483	Highland Specialty Pharmacy LLC
A9-0001484	MedPro Rx Inc
A9-0001485	Pantherx Specialty Pharmacy
A9-0001486	Ardon Health, LLC
A9-0001487	Custom Care Pharmacy
A9-0001488	DMR Pharmacy Inc
A9-0001489	CareSite Specialty Rx
A9-0001490	Lehigh Pharmacy & Supplies, Inc.
A9-0001491	Jack P. Herick Inc, DBA Glades Drugs
A9-0001492	Gentry Health Services, Inc.
A9-0001494	Praxis Rx Pharmacy
A9-0001495	Llife-Q, LLC
A9-0001496	SunQuest Pharmaceuticals Inc.

A motion was made by Mr. Galloway, seconded by Ms. Wallner to approve the ratification of the Non-Resident Pharmacy applications. The motion unanimously carried.

Wholesale Distributor Licensure Approval Ratifications

A4-0002106	Total Pharmacy Supply Inc
A4-0002105	A.P.I Solutions, Inc
A4-0002107	Sun Pharmaceutical Industries, Inc.
A4-0002108	Smith & Nephew, Inc.
A4-0002109	Sun Pharmaceutical Industries, Inc.
A4-0002110	The Procter & Gamble Distributing LLC
A4-0002111	Exel Inc
A4-0002112	J. Knipper and Company, Inc.
A4-0002113	The Procter & Gamble Distributing LLC
A4-0002114	Areva Pharmaceuticals Inc
A4-0002115	Kadmon Pharmaceuticals, LLC

A motion was made by Mr. Galloway, seconded by Ms. Wallner to approve the ratification of the Wholesale Distributor applications. The motion unanimously carried.

Medical Gas Dispensers

A2-0000111 MRB Acquisition Corp.

A motion was made by Mr. Galloway, seconded by Ms. Wallner to approve the ratification of the Medical Gas Dispensers applications. The motion unanimously carried.

Retail Pharmacy Licensure Approval Ratification

None

A motion was made by Ms. Zaragoza, seconded by Ms. Esposito to amend the agenda to add a pharmacist in charge interview. The motion unanimously carried.

Pharmacist-In-Charge Interviews

Ms. Robbins conducted a PIC interview with:
Lorraine Massey, Rite Aid, Millsboro, De.

Consultant Pharmacist Interviews

None

Board Review and Consider of Consent Agreement

None

Review of Applications by DAG

Pharmacy board DAG Eileen Kelly provided guidance on the following disciplinary actions for applications received followed by the board ruling:

Facility: Injured Workers Pharmacy (Andover, MA & Phoenix AZ), a motion was made by Ms. Robbins, seconded by Ms. Zaragoza, to approve the application. The motion unanimously carried.

Facility: WellGistics, LLC, a motion was made by Mr. Sellers, seconded by Ms. Esposito, to table the application. The motion unanimously carried.

Facility: Walgreens Specialty Pharmacy #15443, a motion was made by Mr. Galloway, seconded by Ms. Robbins, to approve the application. The motion unanimously carried.

Facility: Sterile Compounding Pharmacy, a motion was made by Ms. Robbins, seconded by Ms. Esposito, to propose to deny the application. The motion unanimously carried.

Facility: Peterson Rx, LLC., a motion was made by Ms. Zaragoza, seconded by Mr. Galloway, to approve the application. The motion unanimously carried.

Facility: Medical Arts Pharmacy Services., a motion was made by Mr. Galloway, seconded by Ms. Esposito, to approve the application. The motion unanimously carried.

Facility: Alicea Enterprises, LLC., a motion was made by Mr. Sellers, seconded by Mr. Galloway, to approve the application. The motion unanimously carried.

Pharmacist: Maritza Sanchez, a motion was made by Ms. Zaragoza, seconded by Ms. Wallner, to approve the application. The motion unanimously carried.

Pharmacist: Cyril j Okadigwe, a motion was made by Ms. Esposito, seconded by Ms. Zaragoza, to propose to deny the application. The motion unanimously carried.

Pharmacist: David Sherbin, a motion was made by Ms. Zaragoza, seconded by Mr. Galloway, to approve the application. The motion unanimously carried.

Pharmacist: Frances Chin, a motion was made by Mr. Galloway, seconded by Ms. Wallner, to approve the application. The motion unanimously carried.

Pharmacist: Joseph Guan, a motion was made by Ms. Martini, seconded by Ms. Zaragoza, to approve the application. The motion unanimously carried.

CE Approval Requests

Medical Society of Delaware, a motion was made by Ms. Esposito, seconded by Ms. Robbins, to approve the request to become a CE provider. The motion unanimously carried.

Kelly Cantwell-McNelius, re-review, a motion was made by Ms. Zaragoza, seconded by Mr. Sellers, to approve 1.0 credits of the CE request. The motion unanimously carried.

CPR Course Review – Emergency University, Ca.

A motion was made by Ms. Esposito, seconded by Mr. Sellers, to table the request for more information. The motion unanimously carried. Mr. Dryden will reach out to the provider for the requested information.

COMMITTEE REPORTS

Legislative – Joli Martini, Jay Galloway, Kim Robbins, Tejal Patel and David Dryden

No Report

Continuing Education – Joli Martini, Bonnie Wallner, and David Dryden:

No Report

Consumer Affairs – Ken Sellers and Jay Galloway:

No Report

Professional Liaisons – Kim Robbins and Sandra Zaragoza:

No Report

Controlled Substance Liaisons – Joli Martini, Jay Galloway and David Dryden:

No Report

COMMITTEE UPDATES REGARDING PROPOSED REGULATIONS

USP 795 & 797 Committee – Sandy Robinson, Brenda Pavlic, Sandra Zaragoza, Hooshang Shanehsaz, Calvin Freedman and David Dryden:

No Report

Ms. Martini requested at 11:25 am a five minute recess. The board reconvened at 11:32 am.

Pharmacy Technician Licensure Committee – Kim Robbins, Tejal Patel, Kevin Musto, Maryanne Holzapfel, Anne Pyle, Sandy Esposito and David Dryden:

The committee provided draft legislation to be reviewed by the board. The board was asked to review the draft and provide comments back to the committee. Ms. Kelly shared the objective of the committee. The committee is comprised of stake holders as well as board members. The board discussed the need to have a pharmacy technician added to the board of pharmacy if the legislation is passed. A motion was made by Mr. Galloway, seconded by Ms. Robbins, to approve the draft legislation and to move forward in the legislative process of this licensure. The motion unanimously carried.

Collaborative Care Committee – Bonnie Wallner, Cheri Briggs, Cheryl Heiks, Drew Wilson, Deborah Hamilton, Joli Martini, Julie Miro-Wenger, Mark Thompson, Mike Perza, Nick Biasotto, Pooja Dogra, Tejal Patel, Terri Corbo, William Harbester, David Dryden:

Ms. Miro Wenger reported that a meeting of the committee is scheduled for September 3, 2014 at 9:30 am. She would provide a report during the next scheduled board of pharmacy meeting in September.

BOARD CORRESPONDENCE

Mr. Dryden provided the board with the following correspondence via handout:

1. Walmart, Letter Regarding Recordkeeping
2. McGuff Compounding Pharmacy, Letter Regarding Recalled Product
3. NABP, Executes Registry Agreement with ICANN for .Pharmacy Domain.

EXECUTIVE SECRETARY, INSPECTION & PMP REPORT - David Dryden, Michelle McCreary, Samantha Nettesheim

Mr. Dryden reported Michelle McCreary is actively doing inspections. The outsourcing facility application has been created as requested by the board. This will be discussed later in the agenda. An Alert was sent out as requested by the board reminding pharmacists of CE requirements. Mr. Dryden will be speaking at the NASCSA annual meeting this year; Mr. Dryden will also be attending the Executive Officer session with NABP, held in Chicago. Mr. Dryden met with the FDA in Dover, regarding USP 795/797(503b) outsourcing facility requirements. Michelle McCreary reported that regulation 3.4.2 sufficient environmental control, i.e. lighting, ventilation, heating and cooling to maintain the integrity of drugs and devices. The area in which drugs and devices are stored shall be accurately monitored using control devices to maintain room temperature between 59 degrees and 86 degrees Fahrenheit. However the USDA changed these requirements to 68 degrees and 77 degrees Fahrenheit. She will provide all of the required documents to the board attorney for changes.

PMP

Ms. Nettesheim and Mr. Dryden are creating a contract to hire University of Delaware, Center for Drug and Alcohol Studies as a sub-contractor for PMP analysis. Analysis will include geo-mapping controlled substance data with census data to determine at risk populations for overdose and addiction.

Ms. Nettesheim is creating definitions and report parameters for evaluating death data with PMP data. The 2012 data has been obtained from the Office of the Medical Examiners for analysis.

NABP, DPR, Christiana Care Hospital and Cerner will be meeting in the next few weeks to discuss the business alignment to integrate PMP data directly into the CHHS workflow. This would enable prescribers to access PMP data without leaving their workflow. Ms. Nettesheim, Mr. Mangler and Mr. Dryden, along with Cerner, will present a final solution to CCHS administrators in the near future.

Delegate accounts for practice/facility staff to obtain access to the Delaware PMP were launched this week. Providing the option of “delegate accounts” is a recommended best practice for effective PMP utilization. Registration and Query instructions are available on the PMP website www.dpr.delaware.gov.

Tamper Resistant Prescription

Tamper Resistant Prescription Vendors and Provider Verification System are in the process of being updated to ensure the integrity of the Delaware Tamper Resistant Prescription Paper Program.

NEWSLETTER UPDATES

None

OTHER BUSINESS BEFORE THE BOARD

Mr. Dryden presented an example of the “Outsourcing Facility” application. He stated that the application is now available and ready for utilization. Mr. Dryden provided copies of the bills for HS Amendment 1- HB218 signed by the Governor on August 12, 2014 and HB388 Signed by the Governor on August 4, 2014.

Christopher Hamilton, Director and Christa Lee, Team Lead Agreement Monitor of Reliant Behavioral Health provided a presentation to the board regarding the “Delaware Professionals’ Health Monitoring Program”. The presentation included a handout presentation that outlined; the Team, Services Provided, History of the DPHMP, An Overview, and the Use of Technology.

PUBLIC COMMENT

Mr. Musto reported that during the DPS retreat meeting membership, leadership and future legislative concerns were discussed. Mr. Musto explained that the leadership focus was directed at the need to acquire a new executive director. The current Director, Sandra Robinson has turned in her resignation. Mr. Musto informed the board of the following events: Potassium Iodide distribution on August 28, 2014 at the State Service Center. There is a DEA National Drug Take Back scheduled on September 27, 2014. There is a Veterans Stand Down Event in Dover scheduled for October 3, 2014.

NEXT SCHEDULED MEETING

The next meeting is scheduled for September 17, 2014 at 9:30 Am., Conference Room A 2nd floor.

ADJOURNMENT

There being no other business before the board. A motion to adjourn at 12:23 pm was made by Mr. Sellers, seconded by Mr. Galloway. The motion unanimously carried.

Respectfully submitted,

A handwritten signature in black ink that reads "Mast". The signature is written in a cursive, flowing style.

Christine Mast
Administrative Specialist III